

201-14476



NCIC HPV

Sent by: Mary-Beth  
Weaver

05/20/2003 10:09 AM

To: NCIC HPV, moran.matthew@epa.gov

cc:

cc:

Subject: Environmental Defense comments on the proposed category of Linear  
and Branched Alkylbenzene Sulfonic Acids and Derivatives



Richard\_Denison@environmentaldefense.org on 05/19/2003 06:06:00 PM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen  
Boswell/DC/USEPA/US@EPA, adecarvalho@sдахq.org  
cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on the proposed category of Linear and Branched Alkylbenzene  
Sulfonic Acids and Derivatives

(Submitted via Internet 5/19/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov,  
boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and  
adecarvalho@sдахq.org)

Environmental Defense appreciates this opportunity to submit comments on  
the preliminary robust summary/test plan for the proposed category of  
Linear and Branched Alkylbenzene Sulfonic Acids and Derivatives.

The preliminary test plan and robust summaries for the linear and branched  
alkylbenzene sulfonic acids (LAS/ABS) were prepared by the LAS/ABS  
Consortium of the Soap and Detergent Association. The documents cover  
numerous chemicals encompassed by six separate CAS Numbers. Members of this  
proposed category are used as anionic surfactants for the purpose of  
lowering surface tension of water. They are used in home cleaning products,  
laundry detergents, car wash liquids, paint strippers, in bubble products  
for children and in a wide variety of other uses. The diversity of the  
chemicals contained in the proposed category resides in small differences  
in chain length (11-13 carbons), whether the chains are linear or branched,  
whether or not they include a counter ion and whether the counter ion is  
calcium or an amine moiety. In addition, the sponsor proposes to use data  
from two structurally related chemicals to determine if data gaps exist and  
to assist them in developing a final test plan.

The test plan and robust summary, in their current state, are really just  
an interim progress report, given that the sponsor wishes to use data being  
generated under the US HPV Challenge Program and the ICCA initiative to  
complete the test plan. This intent is clearly articulated in the test  
plan. We wish to express our concern about the dependency the sponsor has  
created between completion and execution of this test plan and assessment,  
and progress on the LAS category assessment being carried out under the  
ICCA Initiative through the OECD SIDS Program. While one key bottleneck in  
the latter program's process ? identifying a country sponsor ? has been  
passed (the US is serving as the sponsor country for the LAS category  
assessment), a timeframe for completion of that assessment has yet to be  
determined. Thus, it is by no means clear that the SIDS assessment will be  
completed in a timeframe that is compatible with the sponsor meeting its  
obligation under the US program for the current proposed category, namely,  
to complete all work no later than 2004 so that data can be made public no  
later than 2005. What is the sponsor's intention should completion of the  
ICCA assessment be delayed beyond a point where, by waiting for it, timely  
completion of its HPV Challenge Program obligation would be impossible? In  
our view, the sponsor is obliged to provide the data required under the HPV  
Challenge Program within its timeframe, whether or not the SIDS assessment

03 MAY 20 PM 12:50

RECEIVED  
OPPT/OMC

has been completed.

The sponsor indicates its intention to submit a final proposal for review at a later date and we reserve the right to evaluate the plan when it becomes available. However, we do have some comments on the progress report for EPA and the sponsor to consider as the final test plan is being developed.

1. The available data support a category for the LAS/ABS. These substances are similar in structure, physiochemical properties and they are likely to possess the same spectrum of biological and toxicological properties. This is especially true for the alkyl and sulfonic acid portions of the molecules.
2. The compound of greatest toxicological concern is likely Compound B; the nitrilotris counter ion. Therefore, we recommend that the sponsor use this chemical as the prototype in cases where it is the only chemical with available data for the category.
3. In cases where dermal exposure data are used to fulfill an HPV endpoint, we recommend that the sponsor provide pharmacokinetic data so that the adequacy of using this route of exposure can be determined.
4. The existing repeat dose data appear to be inadequate for this proposed category. There are three studies, but all have significant flaws. The rat study was not conducted under GLP and the histological analyses appear to be incomplete. The monkey study also was not conducted under GLP and statistical analyses are precluded because of the very small sample size. The mouse study examined only liver effects and it also was not conducted under GLP.
5. The reproductive data appear to be adequate for this category, as there were several studies and appropriate reproductive parameters were assessed.

Thank you for this opportunity to comment.

George Lucier, Ph.D.  
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.  
Senior Scientist, Environmental Defense